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July 15, 2019

VIA ECF

The Hon. Tonianne J. Bongiovanni, U.S.M.J. United States District Court District of New Jersey Clarkson S. Fisher Building & U.S. Courthouse 402 East State Street Trenton, NJ 08608

Re: Sun Pharma Global FZE, et al. v. Lupin Ltd., et al., C.A. No. 3:18-cv-2213-FLW-TJB

Dear Magistrate Judge Bongiovanni:

Together with Fish & Richardson P.C., we represent plaintiffs, Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. ("Plaintiffs" or "Sun"), in the above-referenced action. We write seeking the Court's assistance through an order compelling Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Defendants" or "Lupin") to immediately produce non-privileged documents concerning Lupin's internal discussions, evaluations, and responses to on-going interactions with the FDA concerning Lupin's ANDA No. 211239 ("the ANDA")—the very basis for this suit.

Significantly, this discovery dispute does not center on generalized issues of relevance or responsiveness. This dispute is instead borne of Lupin's pattern and practice of concealing relevant evidence through improper manipulation of this Court's rules.

In what appears to have been a means to evade earlier motion practice, Lupin made a false commitment to produce documents no later than July 12, 2019—documents it should have long before produced given their responsiveness to requests served over one year ago. The July 12th deadline came and went, however, with Lupin producing *no documents at all*. Instead, Lupin sent a 6:01pm email—one notably timed such that the Court would be closed for the day—announcing that "Lupin will not be producing documents" and that "Lupin's position has changed…." (Ex. A, Email from Molino to Green, July 12, 2019.)

Stated simply, Lupin executed a strategy of first improperly withholding relevant, responsive evidence throughout discovery, and then purposely misled Sun to evade a motion to compel after the

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evidence was revealed through depositions. That conduct alone warrants sanctions, but multiple factors still further aggravate this situation. First, advised of Lupin's previous efforts to stall, the Court previously instructed Lupin that it must produce documents promptly throughout discovery. Moreover, this is the *second time* in as many weeks that Lupin has promised to provide discovery to avoid motion practice, and then reneged on that promise. Co-pending before the Court is Sun's request of July 8, 2019, to compel the deposition of Mr. Raghu Sharma,

here, Lupin initially ignored a timely served deposition notice, then endeavored to delay motion practice by offering false assurances of its efforts to obtain a deposition date (though not until after close of fact discovery). But there, as here, Lupin later abruptly went back on its word, announcing in a similarly timed close of business email (this one at 5:26pm on Monday July 8, refusing to provide their position any earlier the prior week due to the July 4th holiday, see Ex. B Email from Boda to Fish, July 8, 2019) that it would not make Mr. Sharma available "without a court order."

The motivations underlying Lupin's conduct are without defense. Sun respectfully requests an order compelling Lupin's immediate production of the documents described below, and further requests that it be awarded all fees and costs associated with bringing motions to compel production of these documents and the aforementioned deposition of Mr. Sharma.

I. Motion to Compel Production of Documents

Depositions of Lupin's corporate representatives revealed that substantial internal communications exist discussing the deficiency notices and ongoing formal correspondence with the FDA regarding Lupin's ANDA. Lupin, however, has failed to provide internal documents or communications substantively discussing these recent FDA developments. In fact, Sun has not located *any* email in Lupin's production dated after July 2018, and has only identified less than 200 produced emails dated earlier in 2018—this despite substantial activity between Lupin and FDA during that time. At depositions on June 5 and 7, 2019, Lupin's 30(b)(6) witnesses confirmed that they and others involved would have communicated via email regarding the FDA developments on this ANDA. Lupin's failure to timely produce these documents has prejudiced Sun's ability to properly prepare its case by prohibiting adequate exploration of the scope and status of Lupin's ANDA.

A. Lupin is Concealing Relevant and Responsive Evidence

Lupin cannot and does not dispute the relevance or responsiveness of the documents it withheld. Sun's RFP Nos. 25, 26, 28, 29, 30, and 31, served on June 27, 2018 (Ex. C), expressly seek "documents" related to and concerning Defendants' ANDA. For example, Sun's RFPs seek "[a] complete copy of Defendants' ANDA, and all documents and things concerning Defendants' ANDA,"

¹ The Court issued this instruction to Lupin at a January 31, 2019 teleconference.

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(No. 25), and "[a]ll documents that refer or relate to any communication with the FDA regarding Defendants' ANDA, including but not limited to any documents that refer or relate to the Defendants' ANDA and its approval status." (No. 29). Sun's RFP Nos. 47 and 48 further seek "[a]ll communications between or among any of the Defendants related to Defendants' proposed products," (No. 47) and "[a]ll communications between any of the Defendants and any other person related to Defendants' proposed products." In Sun's RFPs, "[d]ocument" is expressly defined to include "without limitation, *e-mail*, *files stored on electronic media*, *copies of letters*, notes and records of telephone conversations..." (Ex. C at 4, emphasis added).

Sun served these RFPs over *one year ago*, but as best as Sun can determine, Lupin has not produced *any* email communication dated after July 2018, let alone *any* emails that substantively discuss the produced FDA deficiency notices from February 2018, April 2018, and an August 2018 out-right FDA rejection of Lupin's ANDA, which Lupin's witnesses both testified about generally. In total, it appears Lupin has produced *less than 200 emails* from the year 2018 and *zero* emails dated from 2019.²

B. Lupin's 30(b)(6) Designees Confirmed the Evidence Exists and Is Central to Proving Sun's Patents are Infringed

Sun d	leposed_Lı	ipin's	two	principal	corporate	witnesse	s on	June 5	and	June	7,	2019:	Mr.
Makarand Av	achat,												and
Mr. Pramod Dahibhate,											esses		
testified to a	wareness	of rec	ent o	communic	cations an	d develo	oment	ts with	the	FDA	reg	arding	the
ANDA.													

Specifically, the relevant recent ANDA developments include activity stemming from a February 1, 2018,

² Lupin produced email files with productions in January 2019 through March 2019. General practice suggests that at least certain metadata fields should be included with email productions, like Email From, Email to, Email CC, Email Subject, and Date Sent, as well as preserving attachment relationships. (Sun provided these metadata fields with its email productions). Lupin failed to provide any such metadata information with its production, making it particularly hard to identify dates, custodians, and relevant individuals for the email correspondence in the production and to identify what if any deficiencies may exist.

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	. See Ex. F, LUPBRM056550-56.
On April 16, 2018,	See Ex. G, LUPBRM027130. Finally, on August 6, 2018,
	See Ex. G, Ect Bidvio27130. I many, on 7 digast 6, 2016,
LUPBRM031732.	
concerning at least these recent FDA de	ressly identified numerous types of email communications evelopments, all of which would be directly responsive to one 9, 31, 47, and 48, and all of which appear wholly absent from
others at Lupin. Given Mr. Avachat's r Avachat Depo. Tr. at 7:21-8:2), we fin	oduced virtually no emails sent from Mr. Makarand Avachat to role and responsibilities as a selection (see Ex. E, d it unlikely that he would be completely disassociated with the eric equivalent to BromSite® and/or Lupin's ANDA. Further
obligations under the Federal Rules. See prejudiced Sun's ability to adequately of status of Lupin's ANDA, and prepare	its document production constitutes express breach of its per Fed. R. Civ. P. 26(e); 34. Lupin's breach has consequently depose Lupin's 30(b)(6) witnesses, understand the scope and expert opinions. Sun was unable to fully question Lupin's responses, approach, and strategy to address

³ Illustrative of Lupin's inconsistent and deficient document production practices, compare Exhibits G and H, produced without any related internal email correspondence, with Exhibit F, produced with a single cover email reflecting internal distribution of the document, but no further related emails.

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Without production of the recent Lupin documents discussing and describing Lupin's responses to the FDA notices, Sun cannot fully understand or confirm the current and planned composition of Lupin's Proposed Product under the ANDA. Changes reflected or discussed therein could in turn directly impact Sun's infringement contentions, as well as Sun's expert's analysis of infringement. The missing Lupin emails likely also contain comments or information regarding objective indicia of non-obviousness, such as discussions regarding Lupin difficulties in formulation, stability, testing of the composition, or comments regarding the current commercial success of BromSite®, all relevant to Sun's contention (and Sun's expert's analysis of) the validity of the '999 Patent. The parties' opening expert reports are due on July 31, 2019, so expert report work has necessarily commenced. Sun thus requires immediate production of the above-described Lupin documents.

C. Lupin's Discovery Misconduct is Intentional And Grounded in Bad Faith

Sun has made exhaustive efforts to obtain these documents without court intervention, only to be continually frustrated by Lupin's misconduct. Sun requested that Lupin promptly remedy these deficiencies immediately after the deposition of Mr. Dahibhate on June 7, 2019, and then again in written correspondence sent on June 19, 2019. The parties met and conferred on the issue on June 26. Sun requested a written confirmation of Lupin's progress on this search for email and confirmation that production would occur by the close of fact discovery, Friday June 28, 2019. Lupin failed to provide a response. Sun again wrote to request confirmation that Lupin would make a supplemental email production on Monday July 1st. On July 2nd, Lupin finally responded with the affirmative—but now demonstrably false—statement that "Lupin will search for and produce more recent regulatory emails (i.e., regulatory emails from February 2018 to 2019) as soon as possible." (Ex. I, Letter from K. Boda to S. Fish of July 2nd, 2019 at 1).

Given that fact discovery was then closed, and that Lupin still refused to provide a date certain by which it would make production, Sun promptly advised Lupin that the Court's assistance would be required;

Lupin was demonstrably aware that supplementation would be required well before the June 28th fact discovery close, but has yet to offer any commitment as to when it will produce those documents. [Lupin's] position on Mr. Sharma raise still other concerns given that Lupin previously indicated it would find a date for Mr. Sharma's deposition, but has now declined to do so.

In consideration of the case schedule and the upcoming expert reporting deadline, Sun will submit both issues to the Court for resolution at the earliest opportunity.

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(Ex. B, Fish email to K. Boda of July 2, 2019.) Recognizing that Court intervention was imminent, Lupin amplified its initial false promise to produce the documents by tacking on an illusory date by which Lupin's production would purportedly occur:

As described in Katie Boda's letter of July 2, 2019, we should have the updated FDA emails to Sun by the middle or end of next week [July 12].

(Ex. J, P. Molino email to S. Fish of July 5, 2019.) The parties met and conferred again on Wednesday July 10th, *see* Ex. A, with Lupin once more indicating that production of additional documents was forthcoming. As Lupin surely intended, Sun once more relied on Lupin's false statements and refrained from seeking Court intervention. Sun's reliance on Lupin's promise was not rewarded, however, as Lupin waited until after the close of business on July 12 to reveal that it had no intention of producing documents that day due to a sudden "change" in its position. (Ex. A, P. Molino email to C. Green of July 12, 2019.)

Lupin will doubtlessly oppose Sun's request with all manner of assertions as to why the evidence it withheld throughout discovery should now be disregarded. Lupin's effort should fail. If Lupin had a good faith basis to refuse production, it could and should have articulated it long before now. The reason Lupin failed to offer any previous explanation is because no credible explanation exists. To wit, Lupin's last minute email announcing its "change" in position recites but a perfunctory list of non-specific excuses. (Ex. A, at K. Boda email to S. Fish of July 12). Lupin's excuses conspicuously fail, however, to pinpoint any Rule excusing production, nor does Lupin identify any specific undue burden or prejudice that would result. Any attempt by Lupin to retroactively fashion arguments or undue burden, prejudice or irrelevance should be viewed at best as being purely makeweight, and at worst as the capstone of its strategy to evade this Court's rules.

Accordingly, Sun must now seek an order compelling Lupin to immediately produce all electronically stored documents, particularly emails, responsive to at least RFP Nos. 25, 26, 28, 29, 30, and 31 dated from or around February 2018 through to present.

II. Lupin's Bad Faith Conduct Warrants Sanctions

The record shows that Lupin acted in bad faith throughout, making commitments it had no intention of honoring for perceived tactical advantage. Even if Lupin had a meritorious basis to contest production—and Lupin does not—the Court's rules and basic standards of professionalism mandate that Lupin should have announced its position up front. Lupin took the opposite path, opting to contort the Court's meet and confer process for strategic delay. Deconstructing Lupin's motivation for its actions is straightforward. That is, Lupin is betting that even if it loses a motion to compel (as it should), it will suffer no consequences itself, but will have succeeded in prejudicing Sun's infringement case by delaying and effectively denying Sun's access to evidence. This is true of both

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Lupin's knowingly false representation that it would produce documents by July 12, as well as Lupin's illusory offer to produce Mr. Raghu Sharma for deposition.

But Lupin is wrong on all fronts. Courts have consistently awarded sanctions against parties for engaging in the conduct Lupin here displayed, and this Court should likewise follow Rule 37 to frame an appropriate remedy. *See* Fed. R. Civ. P. 37(a)(5) ("If the motion is granted...the court must" require payment of expenses including attorneys' fees absent any substantial justification); *Trowery v. O'shea*, No. 12-6473 (NLH/AMD), 2015 WL 9587608, at *10 (D.N.J. Dec. 30, 2015) (granting in part motion for sanctions, awarding attorneys' fees and costs, stating "[d]iscovery violations that require the parties to reopen or reexamine areas of discovery have been held to be prejudicial and sufficient to require sanctions"); *Cartagena v. Serv. Source, Inc.*, 328 F.R.D. 139, 141 (M.D. Pa. 2018) (granting motion for sanctions of costs and fees where compelled party delayed document production, delayed responses, provided incorrect representations, holding "[w]here that smooth symmetry [of discovery] breaks down, the Federal Rules of Civil Procedure provide that the party who is compelled to expend additional time and resources securing discovery may be entitled to the recovery of their costs and fees associated with procuring that discovery"); *accord. PEG Bandwidth PA, LLC v. Salsgiver, Inc.*, No. 3:16-CV-178, 2017 WL 2992219, at *4 (W.D. Pa. July 13, 2017) ("Because the Court will grant PEG's motion to compel, sanctions in the form of attorney's fees under Rule 37 are appropriate").

For all of these reasons, the Court should award Sun all of its fees and costs associated with bringing this issue to the Court's attention. Sun requests that Lupin be compelled to make its document production within five (5) days of the order granting the motion. Moreover, given the acute scheduling pressure Lupin has sought to create with its delay tactics (Sun's opening expert reports is due two weeks from the date of this letter), Mr. Raghu Sharma should be compelled to appear for deposition in the offices of Sun's counsel within five (5) days of an order granting Sun's motion. Likewise, Lupin's 30(b)(6) designees on subjects related to the withheld documents, Mr. Dahibhate and Mr. Avachat, should be compelled to appear in the offices of Sun's counsel within five (5) days of Lupin's document production requested herein. This accommodation is both fair and equitable, as Sun's counsel should not be forced to incur additional short notice travel expenses owing to a delay that Lupin manufactured.

Sun can be available to attend a telephonic conference on these issues if helpful.

We thank the Court for its consideration of this matter.

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Respectfully submitted,

RIVKIN RADLER LLP

s/ Gregory D. Miller GREGORY D. MILLER

cc: All Counsel of Record (via email)